EXHIBIT 4

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

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TALECRIS BIOTHERAPEUTICS, INC.,	:	Civil Action
Plaintiff,	:	
v.	:	
BAXTER INTERNATIONAL INC. and BAXTER HEALTHCARE CORPORATION,	:	
Defendants.	:	No. 05-349-GMS

- - -

BAXTER HEALTHCARE CORPORATION,	:	
Counterclaimant,	:	
v.	:	
TALECRIS BIOTHERAPEUTICS, INC. and BAYER HEALTHCARE LLC,	:	
Counterdefendants.	:	

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Wilmington, Delaware
Thursday, December, 2006
10:00 a.m.

- - -

BEFORE: HONORABLE GREGORY M. SLEET, U.S.D.C.J.

APPEARANCES:

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THE COURT: Good morning. Please be seated, counsel. Let's start off with a round of introductions from plaintiffs' table.

MR. BOVE: Good morning, Your Honor. Jeff Bove from Connolly Bove representing plaintiffs Talecris and Bayer. I have with me my partner, Mary Bourke, who will be also arguing today. I have our colleague from Ropes & Gray, James Badke, counsel for Bayer, and my associate, Jaclyn Mason.

(Counsel say "Good morning.")

THE COURT: Mr. Rovner.

MR. ROVNER: Good morning, Your Honor. Phil Rovner from Potter Anderson on behalf of the defendants' Baxter International and Baxter Healthcare. With me, all from the firm of Townsend and Townsend and Crew, are Susan Spaeth, Anne Rogaski, and Jim Gilliland.

THE COURT: I take it counsel got the order that I issued yesterday.

MR. BOVE: Yes, Your Honor.

THE COURT: Any questions or concerns?

MR. BOVE: No, Your Honor.

Good morning, Your Honor. Just by way of introduction in terms of the format for the argument today, what plaintiffs would like to propose is a very brief -- I underscore brief -- technology tutorial to set up the

context and to aid everyone. Then we would propose, and we think this is the most efficient way -- we only have essentially one claim -- a limited number of terms, that we would present our arguments, once we have the floor, we would present our arguments, then allow Baxter to present its arguments, and we would propose to reserve just a brief time, if we may.

We really feel that, best-made plans, we can accomplish this in about a half-hour with our opening arguments and try to get through it. I say best-made plans. I think that would be the most efficient way to proceed.

THE COURT: Sounds like it to me. Opposition?

MS. SPAETH: That sounds fine, Your Honor.

MR. BOVE: Your Honor, by way again of introduction, and just so the record is clear, the claims at issue in this lawsuit presently are Claims 1, Claims 7 through 12, and Claims 15 through 20. However, only Claim 1, at least as far as plaintiffs are concerned, is pertinent to today's discussion.

With that, Your Honor, we also thought it might be helpful to provide the Court and Your Honor's staff with a copy of the patent that we tried to enlarge as best we can. These things are hard to read at times. We did apply the actual Joint Appendix numbers to it so it would conform to what is in the record.

And also I would like to hand up, with Your Honor's permission, a copy of our PowerPoint presentation.

THE COURT: Great. Thank you, Mr. Bove.

MR. BOVE: Your Honor, as I also indicated, Ms. Bourke and I are going to split the argument, if that is acceptable to the Court, by dividing some terms.

THE COURT: Perfectly fine.

MR. BOVE: With that, I can simply say briefly that it is plaintiffs' position that Claim 1 should be construed in accordance essentially with its plain and clear meaning.

And, Your Honor, what we did, because we thought a picture was worth a thousand words, we wrote Claim 1 to indicate the construction that Baxter would propose through its claim construction arguments.

If we could see that.

It is not coming out so well. But it is in the PowerPoint presentation.

THE COURT: Does that consist of two binders or one, gentlemen?

MR. BOVE: Your Honor, I gave multiple copies. Just one.

I will let us get right to it and turn the presentation over to Ms. Bourke with respect to the first term.

THE COURT: Great. Are you going to incorporate the tutorial into your discussion?

MS. BOURKE: Yes. I will start with the tutorial, Your Honor. It should only be about five minutes, hopefully.

If we could have the first slide.

What I would like to do is first start with a brief description of what the invention is. Although it often looks complex, it is relatively simple technology. The claim language is not complicated. There are not many technical terms, with the exception of one, perhaps. And then I would like to just go into some of the terms you will hear throughout the morning and explain them to you so that hopefully we are all on the same page.

With that, Claim 1, which is the claim that we will be addressing this morning, is a claim for a method for producing critical life-saving antibody drugs. It is a multi-step process, which includes -- can we go back to the other slide. So it's a multi-step process to make these drugs. But the claim at issue is directed to two steps of the process. The first is the S/D treatment step, that stands for solvent/detergent treatment step, which is a viral inactivation step, which, according to the claim, leads to an elevation in anticomplement activity, which I will address a little bit later.

Then there is a series of additional processing steps, and it ends with a low pH hold incubation step, which then lowers the anticomplement activity.

For now, just understand, anticomplement activity is bad. You don't want it. You don't want to inject patients with a drug that has elevated anticomplement activity.

With that, let's go to some of the terms that you will hear throughout the morning.

Immune serum globulin. Immune serum globulin is a solution of antibodies, derived from blood plasma, given to patients, primarily to supplement defective or insufficient immune systems. The term you will likely hear this morning is IGIV. IGIV stands for intravenously injectable immune serum globulin. What we have here are drugs that are going to be injected into the patient.

And what is an antibody? An antibody is generally a Y-shaped protein, as you can see, that is involved in immune reactions. It binds to antigens, which are pathogens, or foreign invaders to the system, like bacteria and virus, and generally antibody binding activates the immune system.

So basically, what you have here are the solution of antibodies, which are given to people with defective immune systems. They either don't have enough

antibodies or they have antibodies that are damaged or defective in some way, so you need to supplement the immune system.

How are these things made?

You basically start out with collecting blood or plasma. Plasma is the liquid portion of blood with the cells and the other solid material spun out, from multiple donors.

Then you go through a plasma fractionation step. Why do you do that? Plasma contains a lot of proteins from which you can make multiple drugs, Factor 8 being one, which is a drug that is used to treat hemophiliacs. IGIV is another one. Albumin is another one. So you fractionate this plasma to get the desired protein that you want.

Then you go into your downstream processing steps. And you have virus inactivation or removal steps, generally, you have at least two. Then you go into purification of the proteins. That's generally done with column chromatography.

Then you go to formulation, sterilization, you fill it into these vials, then you put it on a low hold incubation, under defined conditions, temperature and time.

So all of the steps of this process will impact the final product.

But what this patent is all about is a virus

inactivation -- if we can go back. What this patent is all about is a virus inactivation step, the S/D treatment step, and the low pH hold step.

So what is anticomplement activity? What I said before is, it's bad. It is the ability of an antibody to bind complement. What is complement? Complement are immune proteins activated by binding to antibodies which are involved in the inactivation of invading pathogens.

There are two ways that you can activate complement.

If we can have the next slide, please.

There is normal complement activation, where you have antibody binding antigens -- the little green triangle is your antigen -- and complement binding antibody, which leads to a desirable immune response. Then you have what we characterize as abnormal complement activation, where you have complement binding antibody leading to an undesirable immune response.

Historically, these undesirable immune responses have been associated with elevated ACA. And what physiological symptoms happen within the patient when they have elevated ACA? You get flu-like symptoms, chills, fever, stuff like that. The more severe reactions are hypertension or anaphylaxis, which can actually lead to death.

So elevated ACA is bad.

What is this invention all about? This invention is about a solution of antibodies which start out to be normal. Then they are subjected to an S/D treatment step. That S/D treatment step damages the antibody, which then binds to complement and leads to an elevated anticomplement activity, which then is subjected to a low pH hold step, which returns the antibody to normal.

So, in sum, we have Claim 1, Step (a), solvent/detergent treatment, leads to elevated anticomplement activity, further process step Claim 1, Step (b), low pH hold lowers the anticomplement activity.

With that, let's just jump right into claim construction, if that is all right with Your Honor.

THE COURT: That is fine.

MS. BOURKE: The first term that has to be construed and that shows up on the proposed claim construction chart is "any virus activity." It is plaintiffs' position that no construction is necessary. It should be given its ordinary meaning. Its defendants' position that any means all. And plaintiffs say the intrinsic evidence establishes that any cannot equal all.

Let's go back to Claim 1 and look at what Claim 1 says. Claim 1 says, A method of treating a solution of antibodies that may have virus activity, the method

comprising, (a), contacting the solution with a trialkylphosphate -- that is the solvent, Your Honor -- and a detergent under conditions sufficient to substantially reduce any virus activity.

So what are those conditions that are sufficient to substantially reduce any virus activity? Those are the solvent/detergent treatment conditions.

If you go to the patent, at Column 1, Lines 49 to 53, it describes that solvent/detergent treatment. This is a prior art method. It was acknowledged in prosecution that this was a method that was in the prior art. It's described in the patent to Neurath, U.S. Patent 4,540,573. And if you look at Column 1 -- I actually start at 45 and go to about 53. It says U.S. Patent No. 4,540,573, to Neurath, et al., which is incorporated herein by reference, describes a viral inactivation process using a trialkylphosphate and detergent process, hereinafter the solvent/detergent process or S/D process.

That solvent/detergent method has gained acceptance as being efficacious in the inactivation of lipid-enveloped viruses with limited adverse effects on biological activity or blood profile.

So it was well-known in the art that what the S/D treatment was inactivating was lipid-enveloped viruses. Just to put that in context, there are also non-lipid-

enveloped viruses that typically are not inactivated by that S/D treatment process.

If you go further into the summary of the invention, which actually describes the invention, it says -- and this is at Column 2, Lines 25 through 30 -- The invention is a method for producing an intravenously injectable immune serum globulin (IGIV) preparation with low anticomplement activity which has been chemically treated to render it substantially free of lipid-enveloped viruses. Substantially free, not all.

THE COURT: Enveloped, envelope, is there a difference? When I read the word, I think of the term enveloped meaning involved. Is there a difference? You pronounce it "envelope." Is that a term of art?

MS. BOURKE: There is a lipid layer that surrounds the virus. What the solvent/detergent treatment does is it inactivates the virus by breaking into that lipid-enveloped outer surface.

THE COURT: Okay. I think we are on the same page.

MS. BOURKE: Further, on the summary of the invention, at Lines 43 to 45, it says, ...the viral inactivation step in a model system results in a substantial reduction, at least four logs, in the titer of the lipid-enveloped viruses.

Again, it is not saying all. It is saying substantial reduction.

Quite frankly, all of this intrinsic evidence was cited by the defendants in their opening brief at Page 6. The defendants well know that the solvent/detergent treatment does not and cannot, is not likely to reduce all viruses. In fact, if you look at defendants' brief, at Page 6, they state, quote, "To maximize the viral safety of purified antibodies, multiple steps can be utilized to remove or inactivate viruses."

Again at Page 8, "In addition to the steps set forth above, manufacturers often employ other downstream processing steps that further purify particular types of antibodies or further inactivate or remove viruses, to the extent they remain after other processing steps."

So any does not equal all, as set forth in the intrinsic evidence, the specification. And defendants well-know that one skilled in the art would not understand the S/D treatment process to inactivate all viruses.

Let me just finish with saying that our proposed construction of that term is any virus activity that is substantially reduced by the conditions of Step (a), that being the solvent/detergent treatment conditions.

With that, I will turn the floor over to my colleague, Mr. Bove.

THE COURT: All right. Thank you.

MR. BOVE: Your Honor, I am going to now address what are claim terms, and I am referring to the claim chart for ease of reference, Terms Nos. 2, 3 and 4. The parties are debating -- and I am not going to repeat the briefs -- what is the appropriate term to construe. I am going to address all of them at one time and just wanted to make that clear.

The term I am going to address is "under conditions sufficient to substantially reduce any virus activity and resulting in an increased level of ACA."

As Ms. Bourke explained, Claim 1 as a whole is directed to the use of a solvent, trialkylphosphate, and a detergent. Baxter's position is that the claim must be limited to a single detergent, cholate, and to be performed under a condition which is a pH at 7.0.

Talecris' position is that the words should be construed according to their plain meaning. Indeed, if we can flip to the next slide, with respect to the conditions, which is the predicate for this term, Ms. Bourke just explained those conditions, the solvent/detergent conditions. With respect to the rest of this phrase, it is our position that the word resulting, the word increased, and the word level mean exactly what they say. There is no need to go beyond the plain meaning of these words, Your

Honor.

It is not a complicated claim term. And we believe that the presumption of ordinary meaning here governs.

Your Honor, to further exemplify our position, if we look at Dependent Claims 19 and 20, you can see in Claim 19 that the detergents that are listed in this dependent claim are polysorbate 80, which is called tween, and sodium cholate. So we know right away that we have a dependent claim which includes polysorbate 80, tween, and cholate. Therefore, under Section 112, the dependent claims are presumed to be narrower in scope than independent Claim 1. It would not be proper to therefore limit Claim 1 to only cholate, because then Claim 1 would be narrower than dependent Claim 19. Again, I am following the order of Phillips, the canons of construction.

Looking next to the dependent claims.

The same thing with respect to the pH, Your Honor. Claim 20 expresses a pH range in Step (a). Step (a), again, is the solvent/detergent step. The range is a pH of between 3.5 and 6. Claim 1 cannot properly be limited to a pH of 7, consistent with the principles of claim construction, or it would be narrower than dependent Claim 20.

That's the intrinsic evidence.

The intrinsic evidence fully exemplifies a range of detergents, Your Honor, cholate, tween, and others. And just for the record, I don't mean to reprint these, Your Honor has these, these are the intrinsic evidence examples, no need to repeat it at this point.

Your Honor, our next point of argument is that Baxter's construction actually reads a preferred embodiment out of the claim. And we know under the Pfizer v. Teva case cited in our briefs that a claim construction that excludes a preferred embodiment is rarely correct.

Your Honor, I am just going to zip right to the intrinsic evidence, at JA-146. This is at Line 4 through 31. There, the specification talks about a pH in the S/D step of preferably less than pH 5.8. Baxter's construction of 7.0 would exclude a preference. It therefore should not be adopted.

Very quickly, Baxter seeks to vary the plain meaning. To do so, it must show a clear and unequivocal expression of disavowal, an expression of manifest exclusion of a restriction in the intrinsic evidence.

What Baxter does, Your Honor, is it attempts to read a word into the claim in order to characterize the increase in ACA. It attempts to read the word unacceptable into Claim 1, and argues that the increase in ACA must be to an unacceptable level.

Reading a word into a claim is a tall order. Phillips so indicates, and the Federal Circuit has so indicated, and the Supreme Court has indicated in the McCarty case at 160 U.S., at Page 116, an eloquent quote, "If we once begin to include elements not mentioned in the claim, we should never know where to stop."

That is the Supreme Court. That is an old case, 1895.

That is basically what Baxter is urging the Court to do, to read a term in. There is no predicate in the intrinsic evidence to do so.

Your Honor, what they do is, Baxter argues that first we should read in unacceptable, and then we should look at the examples and preferences in Column 5 for what is characterized an injust exemplification as to what would be acceptable, and then they say from that, you then know what is unacceptable, and then that should be read into the claim. Of course, the intrinsic evidence refutes this completely. And we have cited this in our brief. We have cited the data in Table 7. We have cited the data in Table 1. You simply cannot read the word acceptable in, consistent with the intrinsic evidence.

In summary, on this term, the claim itself, the dependent claim, the intrinsic evidence, and the canons of construction, confirm that plain meaning is the correct

construction and that Baxter's construction should be rejected.

THE COURT: Thank you, Mr. Bove.

MR. BOVE: I still have more. We will keep going here.

I will now go to Claim Term No. 6, which is the term -- and I am taking it slightly out of order. I am going to do 5 after 6, and I think it will become apparent why, to keep this thing moving.

The term is "then incubating the solution of Step (a)."

Your Honor, Baxter says that there can be no intervening process steps between Step (a) and Step (b). This is wrong. It's wrong for three reasons, at least. Number one, this is a comprising claim. Claim 1 begins with the word comprising. Comprising is an open-ended term. The MPEP, for example, and even the plain meaning of the word, it means including, containing. It is not a term of exclusion.

Step (a) and Step (b) are not the exclusive steps. What Baxter tries to do is to make them such and says that you cannot allow any additional processing steps to occur between Step (a) and Step (b). The word comprising totally defeats that argument.

But there is more, the intrinsic evidence. The

intrinsic evidence at JA-146 and 147, and this is from Column 4, Line 66 to Column 5, Line 44, describes processing steps between (a) and (b).

Finally, Your Honor, if there were any doubt, Ms. Bourke's slide was very instructive, processing steps are how these products are made. They occur between (a) and (b) for a variety of reasons set forth in that slide. Baxter in its brief, at Page 8, acknowledges this. They set it out as well.

In short, then, incubating the solution of Step (a) does not exclude intervening processing steps between Step (a) and Step (b).

Your Honor, I am next going to go to related claim Term No. 5. This is in Step (b). This is the term the "increased anticomplement activity of the solution."

And I can simply say, first, they argue the same arguments that I have just addressed with respect to Claim Term No. 6. I am not going to repeat them. But what is different is one point, the word "the solution," the term "the solution." What is the solution within that term in Step (b)?

If Your Honor follows the argument about comprising and follows the argument that indeed the claim presupposes there will be intervening steps between Step (a) and Step (b) in order to make this medicine, then

necessarily the solution in Step (b) has to be the solution that is incubated. It can't be anything else. It doesn't mean, as Baxter argues, the solution from Step (a), period, without any intervening processing steps.

Your Honor, that is all I have to say on those three claim terms.

I am going to invite Ms. Bourke back up to the podium.

THE COURT: Okay. Thank you, Mr. Bove.

Ms. Bourke.

MS. BOURKE: Two terms left and we are done.

Anticomplement activity. That is the technical term to which I referred before. That terms is defined expressly in the patent at Column 1, Lines 19 through 22. What does anticomplement activity mean? The ability of antibodies to combine, complement. It's that simple.

In fact, Baxter, in their opening brief, when they were describing the technology, described it the same way: "Very generally, the anticomplement activity of the solution is a measure by a particular ACA assay of the ability of the solution to bind complement proteins and thereby initiate these enzymatic cascades in the absence of antigen."

Anticomplement activity means the ability of antibodies to bind and complement. It is a scientific term.

There are many, many ways to measure anticomplement activity. There are hemolytic assays, there are complement binding assays, there are complement activation assays. These are all well-known to those skilled in the art at the time the application was filed.

In fact, the prior art that is asserted by Baxter actually describes some of these additional assays. The assay reference is at Rogaski declaration Exhibit 4, and the prior art reference is at Rogaski Declaration Exhibit 14. Both those prior art references describe C4A generating activity assays. Those are the complement activation assays. They are not a hemolytic assay.

So there are many ways to measure anticomplement activity.

Baxter attempts to import three limitations into the claim for this term. First, they import the particular unit of measure, the CH-50. They import a specific type of assay, a hemolytic assay. And they import a specific type of hemolytic assay, that used to generate data in the '191 patent.

As Mr. Bove pointed out in his argument, once you begin to read limitations into a claim, you never know when to stop. It is improper to import limitations into a claim for a general descriptive term.

Claim 1 specifies neither units nor measurement

techniques. It just describes an elevation of anticomplement activity and a lowering of anticomplement activity. One skilled in the art would know what kind of assays could be used to measure that.

THE COURT: I am curious as to plaintiffs' view, ACA is really a measure as opposed to, let's say, the quality, ability of antibodies to complement. Right?

MS. BOURKE: I am not so certain I understand Your Honor's question.

THE COURT: It is a way to measure? ACA, in fact, is a measure?

MS. BOURKE: I am not so sure I agree with that. I think it's the ability of antibodies to bind complement. It is a scientific event. And what we have in Claim 1 is a qualitative assessment of anticomplement activity going up and anticomplement activity going down.

THE COURT: A qualitative assessment. So we are measuring.

MS. BOURKE: You are measuring by different techniques. But there is no specific measuring technique --

THE COURT: I am not suggesting there is or that the defendant is correct or not. I am just wondering what plaintiffs' view would be of adding the following words to what you propose, and that is, the measure of the ability of antibodies to bind anticomplement?

MS. BOURKE: I am not quite following Your Honor.

THE COURT: It's plain enough to me as a layperson.

MS. BOURKE: I think it would be okay if you are saying, in front of the ability to bind, antibodies to bind complement.

THE COURT: Yes, because, after all, what we are trying to do is instruct a jury as to the meaning of the terms. That is my focus, in addition to or not worrying about what the Federal Circuit is going to do with my claim construction. I am worried about the jury. That is why I ask the question I ask.

MS. BOURKE: I don't think it would be entirely wrong to put the term measured in front of it.

THE COURT: I don't want to just not be entirely right. I want to know if it is helpful, quite frankly, your view as to its impact.

MS. BOURKE: So long as you don't import a particular unit of measure or a particular measurement --

THE COURT: I understand that.

MS. BOURKE: -- technique. That is my only concern.

THE COURT: Okay.

MS. BOURKE: Let me just make certain Your Honor

understands. Anticomplement activity is a biological phenomenon which you can measure multiple different ways.

THE COURT: Let me see if you disagree with this statement. It appears, allaying concerns or not that you might have, this is in defendants' opening claim construction brief at Page 9. It is in the middle paragraph. The defendant writes:

"Very generally, the ACA of the solution is a measure (by a particular ACA assay)" -- I note you disagree with their proposal as to the importation of these limitations. They go on to say -- "of the ability of a solution to bind complement proteins" -- and I will skip the parenthetic -- "in the absence of an antigen.

MS. BOURKE: I don't have a problem with that. But just so we are on the same page, it is a biological phenomenon. It is just like from here to there, I can measure that length in a lot of different ways. I can use meters, I can use feet. But it's a length.

THE COURT: Okay.

MS. BOURKE: All right.

Last claim term, "acceptable level suitable for intravenous administration." It is our position that that term needs no construction. What does it mean? What is an acceptable level? An acceptable level is that which is suitable for intravenous administration. That kind of

language is not uncommon in claim terms. In fact, recently in this district there was a decision construing physiologically acceptable for, in the context of intravenously administrable drugs. That is Pharmacia v. Sicor, if you want the cite it is 447 F.Supp. 2d 363. That was this year.

The intrinsic evidence supports that. The intrinsic evidence at Column 5, Lines 51 to 54 states, quite clearly, why there is no strict rule for determining when the ACA level is low enough to be an acceptable level suitable for IV administration. IGIV preparation should have ACA levels as low as possible. ACA levels are tied to adverse reactions. Any clinician will know what is acceptable for IV administration. There are no numerical limits in the FDA regulations, because it is all determined on a product-by-product basis. We will have evidence at trial from clinicians talking exactly about this term.

And with that, unless Your Honor has any further questions, I will turn it over to --

THE COURT: No, I don't.

MS. BOURKE: -- the defendants to my left.

THE COURT: Ms. Spaeth.

MS. SPAETH: Good morning, Your Honor.

Your Honor, if I may take a minute to switch the electronics.

THE COURT: No problem.

MS. SPAETH: We also have a presentation. May we please hand Your Honor up some material?

THE COURT: Please do. Pass it up to Ms. Walker there.

You have the floor.

MS. SPAETH: Thank you, Your Honor.

While plaintiffs refer to Phillips, they actually do not follow the teachings of Phillips. I don't think we heard plaintiffs mention the prosecution history once. The claims have to be construed in light of the claim language, the specification, the prosecution history, and in fact they have to be construed in terms of how a person of ordinary skill in the art would understand the claims at the time of the invention.

Here, we believe that a proper Phillips construction gives you Baxter's construction.

Plaintiffs' analysis is improper for several reasons. First, they improperly pick and choose among the intrinsic evidence. We heard them talk about ACA being low enough, but they haven't put any context with that. They certainly haven't put the context with that, that is, throughout the specification and the prosecution history.

They also purport to say, to talk about an ordinary meaning. But what they have really done is they

have used a dictionary definition, because they haven't put the ordinary meaning in terms of how one of ordinary skill in the art at the time the invention was made, they haven't said it in that context. They haven't even told us what they propose the person of ordinary skill in the art to be. Instead, they have converted it to a dictionary definition. But they are quite right, of course, they don't use the word dictionary definition, because that has been clearly disavowed by Phillips.

What we would like to do is spend a few minutes on Claim 1 and the basis of the claim, just touch on a few points in the specification and file history, and then go to a few particular claim terms.

THE COURT: That is fine.

MS. SPAETH: Claim 1 is the only independent claim. It is on the slide. But in order for me to keep going, I thought at the same time we had it on the slide I could put it on a blowup so I could keep the slide together.

THE COURT: I have it right in front of me.

MS. SPAETH: Your Honor, may I approach the board?

THE COURT: You may.

MS. SPAETH: As plaintiff said, the claim is directed to a method of treating a solution of antibodies and includes a solvent/detergent step and a low pH

incubation step. The solvent/detergent step, you will see, requires that the solvent/detergent results in an increased level of ACA but that increased level must be to an unacceptable level.

Now, as Ms. Bourke spoke, the solvent/detergent step was well-known. She cited this section of the file wrapper, she cited Neurath. If you look at this section right here, you see that Neurath talks about, described a viral inactivation process using trialkylphosphate and detergents and that that method, the solvent/detergent method, has gained acceptance as being efficacious in the application of lipid-enveloped viruses.

Now let's look at this claim, their claim, contacting the solution with a trialkylphosphate and a detergent under conditions sufficient to substantially reduce antivirus activity. This phrase right here, at least in this claim to here (indicating), looks very much like the prior art.

They have also admitted that the Talecris process is prior art.

They talk about the Tenold patent here also in Column 1. They say, Tenold reported a method of preparing an immune serum globulin with low ACA. Which could be administered by intravenous injection. Going to their claim now, we see Step (b) talks about an incubation step under

conditions such that the increased ACA of the solution is reduced to an acceptable level suitable for IV administration.

Very similar language to that which they admit is prior art by Tenold.

So given that, the scope of the invention here is actually quite narrow. The alleged invention demands that both the solvent/detergent step increase ACA to unacceptable levels followed immediately by a pH step that decreases ACA to acceptable levels. Plaintiffs now dispute this interpretation, that the increase has to be unacceptable. But a logical reading of Claim 1, which we will go through, gives that interpretation. That is what Bayer set forth in their specification, as we will see in a minute, and that is what Bayer argued to get this patent allowed to the examiner.

They talk about low and they say, it just has to be low enough for IV administration. But actually, in their specification, they go beyond that. You would see here, in Column 2 now, here is where they talk about what they found: We have found that using the S/D process -- it begins at Line of 6 -- using the S/D process to treat ISG preparations, especially those formulated according to the Tenold '608 patent, results in a product with an acceptable viral inactivation but unacceptably high levels of ACA.

This is not high or low. It is unacceptably high ACA. They have said, this is what they have found from the solvent/detergent step. That is the only thing new that they claim to have discovered by a solvent/detergent step.

Similar language is in Column 9. Column 9 of the patent, beginning, at Line 38, says, it's right under Table 7, Taken together, the above result suggests that ISG products which have been subjected to a solvent/detergent viral inactivation process resulting in an undesirable ACA increase can be made suitable for IV administration by incorporating an additional incubation step under the conditions described here to reduce ACA to an acceptable level.

So this provides some of the context from the specification. They completely ignore the prosecution history. However, during the prosecution of this patent, they had to make arguments that involve the term acceptable level as well as the term increased level of anticomplement activity in order for the claim term to be allowed. They completely ignore those here.

Your Honor, I would like now to talk about three claim terms in particular, if I might, and to walk through the evidence.

THE COURT: Yes.

MS. SPAETH: We believe there are three claim

terms critical and potentially case-determinative in here. Just so we keep track of them, the first claim I am going to talk about is increased level of anticomplement activity. That is right here at the end of Step (a). Then we are going to talk about acceptable levels suitable for IV administration, and that is here at the end of Step (b). Then I would like to also address the then incubating the solution of Step (a). We don't mean to give up our other constructions at all. We just mean to try to focus today's construction.

I am prepared to answer questions, I hope I am prepared to answer any questions the Court may have by any of the other claim terms.

Increased level of anticomplement activity here is the last phrase of Step (a). And in light of the argument, and the claim language, we propose that the construction means that this solvent/detergent step results in that gets increased, the anticomplement activity, from a level acceptable for administration to unacceptable. That is that this solvent/detergent step ends up with an unacceptable level of ACA, not just any level, not just any increased level, but somehow, it has to be an unacceptable level, as the plaintiffs have defined it.

This construction is compelled by the language of the claim. We see the claim term here, but of course,

remember, with the art that this step is generally known and an incubation step is generally known, we will see in the specification and in the prosecution history that the purpose of Step (b), this incubation step, was to incubate the solution such that the increased anticomplement activity of the solution is reduced to an acceptable level suitable for IV administration.

For Step (b) to have meaning, the increased level in Step (a) must be to an unacceptable level so that Step (b) has the opportunity to decrease it to an acceptable level. Step (b) would have no purpose if it was going from acceptable to acceptable. In order for Step (b) to have meaning, it has to go from unacceptable to acceptable.

Thus, the increased level here in Step (a) must be to an unacceptable level.

Now, this is supported by the specification as well. We saw here at Claim 2 that they found that when they used the S/D treatment, it resulted in a product with an acceptable level of viral inactivation but unacceptably high ACA. I just also read a portion of Column 9, which I am not going to re-read. At Column 9, that is where you saw that the solvent/detergent step resulted in an undesirable ACA. And now if you look at Column 10, they speak at Line 24, It would be desirable to produce substantially virus-free IGIV. That means, we like to use the S/D step, but following prior

art, it results in a product with an unacceptable level of ACA.

So not just any increase. How are we going to measure an increase? It has to be an increase to an unacceptable measure of ACA. Plaintiffs would like us to believe that it could be any increase. Low, low is better. The lower, the better. But what's low compared to?

Well, continuing here in Column 2 -- sorry to jump around -- they first talk about how the prior art results in unacceptably high levels of ACA. They go on and they say elevated levels were always detected at the sterile bulk stage, always detected.

They also had elevated levels.

What did they mean by that? Did they mean it went from 25 to 26? No, that's not what they meant.

They were talking about, this is in the context of unacceptably high ACA, a few lines down, beginning at Line, I am not sure if it's 14 or 15, Preparations of ISG with high ACA levels are not suitable for IV injection but instead you have to inject it intramuscularly.

So this is not low compared to I want it to be as low as possible. This is low as compared to high. And high is unacceptable and undesirable, as they stated over and over in their specification.

The prosecution history now also demands

Baxter's construction. All of the claims were initially rejected in the first office action. There is not too much special with that. But faced with those objections, Bayer made certain arguments to overcome the objections. One of the arguments Bayer made was it added the word increased. This word increased wasn't original. It was not in the first claim. It added the word increased in order to get the claim allowed.

Now, on Slide 18, we see Bayer's response as it was adding this word increase. It argued the origin of the invention is the discovery by applicant that using the trialkylphosphate detergent viral inactivation method of Neurath for immunoglobulin preparation resulted in a surprising -- that is the hook of their whole invention -- a surprising but undesirable increase in ACA.

What is undesirable? Undesirable means it is not suitable for IV administration. This increase is now a requirement in Step (a) of the claimed methods. It is a requirement that it increase, and the increase here is described as an undesirable increase, not just a few points here and there.

They go on in their argument, in Step (b), The invention requires that the product of Step (a) be incubated under conditions sufficient to bring about a decrease in ACA to an acceptable level.

That is where I started with this term, you see, that the purpose of Step (b) requires that the increased ACA be decreased to an acceptable level. For the entire claim to have meaning, the increased ACA in Step (a) must be to an unacceptable level.

The examiner actually didn't buy that argument, yet. The examiner kept rejecting the claims, so much so that they had to appeal to the Board of Patent Appeals at the Patent Office.

In their appeal brief, they further say, If there is no such increase, that is, the increase in ACA due to the solvent/detergent step, If there is no such increase, then Step (b) of the invention, and the invention itself, is not even needed.

They are clearly defining the invention as seeing this solvent/detergent problem that has raised, they say, to unacceptable levels, such that they have to have an incubation step to lower the ACA to an acceptable level.

It is those arguments that they made to the Patent Office, and that is how they got this claim issued.

Now, they don't talk specifically today, but they referred to it generally, that their data just shows raised. Not all the data, not all the data shows that it's raised to an unacceptable level.

Now let's look at the figure. Originally, the

figure is the second page of the patent, and in your copy that they gave you or you already had from the file, you will note that your figure looks like this. It has three bars. But the figure as originally filed didn't have this bar. It only had these two bars.

THE COURT: For your record, you mean the middle and the bar to the far right.

MS. SPAETH: Thank you, yes. For the record.

It had the incubation bar, the middle bar, where the anticomplement activity level is at 60. And it had the width incubation bar, the bar to the far right, with an anticomplement level that looks about 23, give or take.

Now, if we look to the patent, the patent describes Figure 1. In this brief description of the figure, in Column 2, after the background and summary of the invention, they briefly describe the figure. They show, they say, Fig. 1, which is the only figure, Fig. 1 shows a comparison of the typical average observed ACA levels of five percent IGIV solutions treated according to the S/D process and with or without followup incubation of the present invention.

So they say that this is the average data, and this is after the solvent/detergent with incubation, after the solvent/detergent without incubation.

Now, they actually don't point to any particular

average data, like you can't find the number 60 anywhere in the patent. But if you average the numbers, if you go to Table 7, which I don't think we need to do for this discussion, but if you go to Table 7, you can see that the average ofA1, A2, A3 and A4 at the zero numbers is 60. You can find the average if you do a little math. But they don't actually tell you an average. They just say, this is an average. But they have told the examiner what an acceptable level of ACA is regarding five percent. You will see in a minute that that acceptable level at five percent is 45.

During the prosecution, they had to argue hard to get this claim allowed. And as part of their argument, they revised the figure to now add a new bar, the leftmost bar, that they labeled Control Tenold. And it has a bar with an AC activity of 25. They talk about the control being the standard, the so-called standard, from which to measure any increase in ACA. That is how they talk about it in the file history.

Now, when you look at the claims, they make sense against this figure, now that we have seen from putting together the file history.

The control bar provides this so-called standard that this is -- this did not have an S/D step. No S/D. So without S/D, they did their processing, and they measured

the ACA and they got 25. Then they rely on this figure throughout the prosecution history, saying, then they added S/D, and when they added S/D they got these high ACA numbers, and the average of a certain set of those ACA numbers was above that acceptable for administration. So this is with S/D, but before incubation.

So you see, it shows an increase of above that which is acceptable.

Then, they say, but, then they added the incubation step and the ACA went down and now it was acceptable again.

Plaintiffs can now not be held to the arguments that they made during the prosecution history.

THE COURT: Did you misspeak? You meant plaintiff should be held?

MS. SPAETH: Yes. Thank you, sorry, Your Honor. I appreciate that.

Plaintiffs cannot ignore the prosecution history, that they must be held to it. Thank you.

And actually, if you look at sections of their brief, they agree with us. We have three quotes here on the board. They admit that Dr. Alonso surprisingly discovered that S/D-treated IGIV failed to meet release specifications because the ACA had elevated and was too high.

Guess what the release specification is? 45

(indicating).

The S/D process results in ISG preparations with acceptable viral inactivation but with unacceptably high levels of ACA. That's from their brief. And then, using a final incubation step would surprisingly lower ACA to an acceptable level suitable for IV administration.

We believe that the claims, the specification, the file wrapper, as well as their own statements, make it clear that Baxter's claim construction should be adopted by the Court because it is proper.

The second term I would like to talk about is acceptable level suitable for IV administration.

Acceptable doesn't sound like a very complicated word. But when you are talking about ACA, everything is complicated, unfortunately. It is very complex, because it is not simply measuring the -- ACA is not like measuring the length from the podium to the jury box. Everything we think about ACA is more complicated. We understand from Your Honor's order that you don't wish us to talk about our general position on indefiniteness, so we will skip that.

THE COURT: Not at this time.

MS. SPAETH: We will go to our alternate construction that we provided to the Court.

We believe that for acceptable levels suitable for IV administration to be understood by a person of

ordinary skill in the art at the time the invention was made, 1995, that a defined numeric level is necessary. But the defined numeric level doesn't tell the whole story. You have to have the numeric level as well as an identification of the assay used.

Without reference to both the numerical level and the identification of the assay, acceptable level suitable for IV administration lacks meaning to a person of ordinary skill in the art.

They might not -- they certainly know they don't want to kill anybody. But the claim is not discussing let's have an ACA level just low enough not to kill anybody.

So we are now back to Claim 1 and we are talking about the last phrase of the claim in Step (b), intrinsic evidence is required to look at what acceptable level means. And it's pretty clear from that, the numerical limitation, that is. In the specification, at Column 5, Your Honor, Column 5, the paragraph that starts at Line 56, first you see the sentence that says, The figure depicts the typical average reduction of ACA observed in five percent solutions following S/D treatment.

So remember that figure that I said. That's the only figure. And we are again talking about acceptable, or the reduction. And here is where we see the acceptable level 45 that I drew on that figure.

For a five percent ISG formulation, the acceptable level suitable for intravenous administration, preferably, would be less than about 45 CH-50 units per milliliter and more preferably less than about 30 CH-50 units per milliliter. For a ten percent ISG formulation, the acceptable level suitable for intravenous administration preferably would be less than about 60 CH-50 units per milliliter, and more preferably less than about 45 CH-50 units per milliliter.

That 45 line comes straight here from the specification itself.

Now, keeping with the numeric portion that's necessary for the claim, we can look at the file history.

Not only did the examiner initially reject the increased level as indefinite, she also rejected the claim acceptable level as indefinite. And, in fact, in the prosecution history, she said, The metes and bounds of what is defined by an acceptable level cannot be determined.

That was her first office action after the case was filed.

Now, Bayer's response, that same May 1996 response, they also argued what an acceptable level should be. Bayer argued the acceptable level of ACA generally depends on IGIV concentration. And examples for five and ten percent solutions are described in the second full

paragraph of Page 9. That's Page 9 as filed.

I am not going to re-read the second paragraph of Page 9, which, Your Honor, what I just read from Column 5, beginning at Line 56, this is the second paragraph of Page 9.

Now, in their brief, they cite the prior paragraph and say, oh, they were only concerned about lowering ACA. And they cite to this, the preparation should have ACA levels as low as possible. That is not what they argued to the Patent Office to get this claim allowed.

The Patent Office said, acceptable level is indefinite. It is ambiguous. And in order to get over that hurdle, they did not say look. They said five percent means 45. Ten percent means 60. This is the section of the patent that they relied on to get this claim issued.

And the examiner withdrew her objection based on that argument. The very next office action, she withdraws her objection to indefiniteness regarding acceptable level. She says, Further, it was argued that an acceptable level is not vague because it depends on the concentration of IGIV. The latter argument is found to be persuasive, and the rejection based on an acceptable level suitable for intravenous administration is withdrawn based on the definition of an acceptable level found in the specification at Page 9.

For the claim to be allowed, the numerical definition was a must to the examiner. Bayer set forth what was an acceptable level for five and ten percent solutions in the specification at Column 5. It argued that section of the specification at Column 5. It gave the numeric input to the examiner. It made that argument for the patentability of the claims. And their argument was accepted by the examiner in 1996.

They cannot now run from their earlier statements and positions. This numeric information must inform the meaning of acceptable level in this case.

Indeed, a person of ordinary skill in the art reading the patent would look there and they would look at that section of Column 5 and see the language, an acceptable level means 45, not a five percent solution. Somebody of ordinary skill in the art would plainly know how to read that, except they are still missing the identification of the assay.

Now, I think it was Ms. Bourke, but if I missed who said what term, I hope counsel will forgive me, they talk about how prior art assays and I think they disclose other ways of measuring bad things happening in the complement system. We suggest that other prior art is necessary to understand where a person of ordinary skill in the art is coming from and how somebody would look at the

numbers that, that section of Column 5, and look at the claims in figuring out what is an acceptable level.

This is a table from a Bayer paper published in 1989. And this table is from that paper. It measures AC activity under two methods, Method 1 and Method 2.

Let's first read the bottom bar. With Method 1, an acceptable level is considered to be below 25 units. So Method 1, some assay, has an acceptable level at 25 units, while Method 2 has an acceptable level of below 20 units.

They at Bayer looked at ten lots. And they did the Method 1 assay and the Method 2 assay. And the Method 1 assay, which has an acceptable level of 25, all of the ten lots passed the Method 1 assay. All of the ACA levels were found acceptable. They were all less than 25 units.

Under Method 2, which had a different acceptability level, had a 20-unit acceptability level, look, all of them failed.

So depending on which assay you used and the limits of that assay, each assay has its own limits, you would either think you had a lot that was acceptable or a lot that was unacceptable.

In addition, they don't even correlate between the two.

So let's look at the first lot with Method 1. It has an AC of 11.9. The second lot has a higher ACA,

12.8. But look at Method 2. The first lot has 25.3 and the second lot has a lower ACA under the other assay. So it's not that they all go up or down together. It's not like you can say Method 1, say I multiply by 2.4 and I get the Method 2 method. No, they are not correlated.

You see Lot No. 3 has the same level as the first lot under Method 1. But under Method 2 the assay gives a value in between the value given for Lots 1 and 2.

So you see, Your Honor, not only is acceptable defined for each particular assay, but assays do not correlate among themselves and you don't know what is acceptable unless you know the assay. The assay determines acceptability along with the numeric values.

That is how we came to our construction, Your Honor. Our construction requires a defined numerical level and the identification of the assay used to obtain the ACA value, because that is what a person of ordinary skill in the art would need to know in order to judge whether he or she infringed the claim.

THE COURT: I will wait until you finish.

MS. SPAETH: One last claim term: then incubating the solution of Step (a).

Baxter's proposed construction is, then incubating the solution of Step (a) is right here at the beginning of Step (b). And we propose that the construction

be incubating the solvent/detergent treated solution resulting from Step (a) without any additional processing steps between Steps (a) and (b). They have just about the opposite construction, Incubating a solution originating from Step (a) under these certain conditions wherein additional steps may be performed prior to said incubating.

Now, their first complaint against our construction is that we are ignoring the word comprising. Baxter does not ignore the word comprising. And I am here telling you how we are not.

They are right that, in general, comprising is open-ended. But comprising, just because you have comprising in the preamble doesn't mean that you can ignore the other parts to the claim.

What they are asking the Court to do is to ignore them and ignore the solution of Step (a).

Here is what I mean by that.

A patent attorney can write a patent, can write a claim that says, a method of treating a solution of antibodies wherein you have an S/D step and you have an incubation step, without regard to which comes first or the immediacy between them. That is a very open-ended claim. You just have an S/D step and an incubation step. This doesn't say that. This has the word then in there, so they could have written the claim, you have an S/D step followed

by or then you have an incubation step, so that the order of the processing steps, first an S/D step, then an incubation step, is required by the claim. That is what this then provides.

Here they didn't do that. They went further. They said, then incubating the solution of Step (a). It's that language that's limiting whether or not they get intervening steps.

Now, this comprising still has meaning. It may not be the only steps in a process. They might actually fractionate first. They might remove the solvent/detergent immediately after incubation. They might formulate it here. Just because at Bayer in their operations and Talecris have the incubation step last doesn't mean you have to do it that way. They chose to use these words, the solution of Step (a). They did not have to do it that way.

These are the words that limit, and we are not discounting comprising. Lots of other things can still happen in the process. It just can't happen between Steps (a) and (b).

We have a graphic that hopefully can help illustrate our point.

If you look at the three beakers in the top row, Your Honor, we suggest that these three beakers represent Claim 1 as properly construed. You first have the solution,

it's clear, in the clear solution in the graphic. And then you do Step (a). Step (a) is the solvent/detergent step, and it results in unacceptable ACA. That is reflected by a blue solution. Then you incubate that step, then you incubate that solution, the solution of Step (a), and when you incubate it in Step (b), now you have acceptable ACA.

So the solvent/detergent treatment did something funky and it increased the ACA to unacceptable levels, and now the incubation step is reducing the ACA to acceptable levels. That is what Claim 1 reads.

Bayer would have you believe that additional steps can be between Steps (a) and (b). However, if there are additional steps -- let's say there is now a Step X. What if Step X makes the solution acceptable for IV administration? In that instance, Step (b) is unnecessary. That is not the flow of Claim 1. Under their construction, they leave open that this Step X can affect ACA, and if Step X makes it acceptable, they are outside the scope of Claim 1.

Now, Your Honor, they knew how to write a claim differently. In Europe, they added removing the solvent/detergent in between their first step, their S/D step, and their incubation step. They knew how to write a claim differently. They chose not to do so in the U.S.

Moreover, this isn't just a side point. They

say here: removing trialkylphosphate and detergent from the second antibody solution to produce a third antibody solution.

So they are saying that the removal of S/D is changing the quality of the solution. And they have given a new number, the third antibody solution.

If they wanted to write the claim differently, they knew how to do so.

They chose instead to say, then incubating the solution of Step (a).

Your Honor, I am happy to take any questions or to talk about any other claim terms that you might --

THE COURT: I have a specific question to your argument, the defendants' argument. Then I would like to have a discussion with both parties about the person of ordinary skill in the art. I want to talk about that a little bit and get your views as to the role, because you both referred to the person of ordinary skill I think appropriately. I think as directed by the Federal Circuit, starting with the claims, or at least starting with the claims and moving right onto Phillips, which directs trial courts I think to begin our task of interpreting claims with the language of the claim words and to try to divine the meaning of the words from the point of view of the person of ordinary skill.

Is that a fair statement, sort of a hornbook statement of claim construction at the beginning?

MS. SPAETH: Yes.

THE COURT: Yet it seems that perhaps, at least one party, I am not sure, maybe both of you would view -- I don't think the Federal Circuit views it differently -- that the Court needs to understand that term, what that means, what that person of ordinary skill in the art, what the definition is for any given dispute.

Does that put the Court in the position of considering, and appropriately it would be in my view extrinsic evidence, where the parties are perhaps not in agreement as to the meaning? Because it is written, I think it has been written in this case, or suggested at least, in this case -- I will give the plaintiff a chance to comment on this -- that I would be in a position, I would put myself in a position of considering extrinsic evidence.

I don't mean to go on.

MS. SPAETH: Your Honor, I believe what Phillips contemplates when advising what the level of skill in the art is is along the lines of the background: Where is the state of the art? What would somebody know about the state of the art as of September 1995 in this case?

THE COURT: And I share that, right. I left that out. That is fine. That is important.

MS. SPAETH: What I meant to say is that this state of the art, the background technology, can inform the Court, that the Court has a tough job. You have to put yourself back in time and you have to know what one of ordinary skill in the art would know. And that means that you are able to look at the background of the technology and the state of the art at the time. And with that sitting there, we believe you can still construe the claims just with the intrinsic evidence. But you must take into account the state of the art, the background technology, where the level of ordinary skill person would be sitting in order to then look at the intrinsic evidence and construe the claims.

THE COURT: I need to understand each party's view then of what the level of skill was at the time of the invention. Is that correct?

MS. SPAETH: I believe, Your Honor.

THE COURT: Does that put me in the land of extrinsic evidence?

MS. SPAETH: I do not believe so. I believe that is part of what was required by Phillips.

THE COURT: What is Baxter's view as to the person of ordinary skill of the art?

MS. SPAETH: It is in our opening brief, Your Honor, at Pages 18 and 19. And we believe that a person of ordinary skill in the art would be a process chemist or a

biochemist or an immunologist, someone in this general field, with either a Bachelor's degree or a Master's degree, and we list several things, like chemistry, biology, biochemistry, immunology or related field. Those general types of fields. And several years of experience in one or more of the following. The purification of blood proteins, how you go from blood plasma to the intermediates, or viral inactivation or removing viruses when everybody knows that is important and that was of utmost importance, as you might appreciate, in the eighties and nineties.

They would have had in 1995 some exposure or experience with solvent/detergent treatment and low pH incubation, if they met the virus removal part of the prong, and/or ACA anticomplement system, including how to measure and lower ACA, or the equivalent.

So the general field, we do not believe it has to be a Ph.D. We do not believe it has to be the world's leading expert on any particular one of these. But somebody who is generally working in the field.

THE COURT: It doesn't have to be one of exceptional skill, but ordinary skill.

MS. SPAETH: Correct.

THE COURT: Let me ask you this: You point out, I think it's Column 5, the patent discloses certain specifics in the assay. I guess my question is, absent that

disclosure, could plaintiff have enabled independent Claim 1?

MS. SPAETH: We believe it would not have passed the written description test, Your Honor, because it was found to be indefinite until they pointed to this section of their specification.

So without the numeric values, they failed the written description. Without the assay identification. They would fail the written description and the enablement prong, yes.

THE COURT: One of the concerns that I have about a number of Baxter's arguments is, it would seem to me that it might place the Court in a position, I am not sure, of limiting the claims by the preferred embodiment or the disclosures in the specification. Do you want to address that?

MS. SPAETH: Sure, Your Honor. I know that it is a concern of plaintiffs that we suggest that claims must be limited, for instance, to cholate and pH 7 rather than including tween or any other detergent or pH 5.8.

First, on the cholate, while they say they have this tween example in Table 1, if you read the full specification, it becomes clear that Table 1 is only talking about raising ACA with an S/D step. It doesn't talk about the second half, which it is needed for their claim, which

is the lowering of the ACA with an incubation step. There is no tween data for Step (b) of their claim. Thus, there is actually no tween data to the full scope of the claim.

So we believe that we are right for many reasons, including extrinsic evidence, you don't want us to talk about, but even with the intrinsic evidence.

THE COURT: I concede, by the way, that sometimes when I have these arguments it seems rather artificial for me to say what I think the Court has told us to do, and that is, only in certain circumstances consider extrinsic evidence. And I rather avoid and have been comfortable staying within those parameters because I have entertained arguments, not knowingly perhaps, but where we have injected summary judgment considerations into my Markman process. And it is somewhat seductive, actually. But I am not sure that it really results in a correct approach to claim construction.

That is just my views.

I don't want you to feel like I have got my head in the sand on this. It's not that you have to feel that you are going to blow up if you step on extrinsic evidence terms.

MS. SPAETH: We will generally stay away from it.

So on the tween issue itself, there is no data

in the patent about tween vis-a-vis the entire claim. So we feel pretty confident that there is no support for the entire scope of the claim vis-a-vis tween, which leaves us with cholate. There is no other detergent discussed besides cholate for both Steps (a) and (b).

Then on the pH 7 and the pH 5.8, Table 1 and then Tables 3 and 5 are all with pH 7. And when you look at the ACA value, boy, those go right up there. They zoom up there. They apparently go off the chart of the assay. When it says greater than a hundred, Your Honor, I think it means the assay can't tell you the number. It's top of the chart, so to speak.

So pH 7, all the ACA numbers go above. And then they work to bring it down through a low pH incubation. But if you look at the data to pH 5.8, you see that they are not all off the chart. You see 43, 31 and 44. Those are all five percent solutions. Of course, they are all less than 45. So when you look at how they had to argue acceptable, and you read the whole specification, you see, this is acceptable, and at least 43, 31 and 44 are acceptable at day zero, before any incubation, since it is before any incubation, it is outside the scope of the claim. Again, you don't need to lower it.

For a ten-percent solution, this figure doesn't apply, because this is a five-percent figure, for a

ten-percent solution, acceptable was 60.

So at day zero, they have 49 and 53. Those are all already acceptable levels suitable for IV administration.

They do say lowest possible, lowest possible. And we admit in the spec they do also talk about wanting it low as possible. But that is what the examiner had a problem with when the examiner looked at the term acceptable level, and it didn't make clear that numeric value, she said it's indefinite.

So just because we have this number that is more than twice this, and this number, which is about three times that, just because we have outliers, we do not believe that a person of ordinary skill in the art would look at those outlyers and say, oh, 5.8 doesn't work. We think a person of ordinary skill in the art would say, yep, 5.8 does it.

They say, well, if we limit, when they talk about their preferred embodiment and they refer to Column 4, Your Honor, they were talking about the reference in the patent to the preferred embodiment for viral inactivation. They say that a lower -- that pH 5.8, maybe 5.6, with cholate gives better viral inactivation. And so their complaint to us is that we are cutting out the preferred embodiment.

Your Honor, I can't hold back. Their data does

not support pH 5.8. It simply does not. What is claimed is something that increases ACA to unacceptable and then decreases it to acceptable. If there is data that is already acceptable, there is no meaning to Step (b). It's clear from all their arguments that that step had to reduce it to an acceptable level.

THE COURT: Okay. Thank you.

Why don't we take a short break, and then come back and I will hear plaintiffs' rebuttal.

(Recess taken.)

THE COURT: Mr. Bove.

MR. BOVE: Thank you, Your Honor.

Let me first indicate the approach I would suggest for rebuttal, so we are organized here. I am going to take the terms essentially that I took in the opening. Ms. Bourke will take her terms as I follow.

THE COURT: That is fine. But I do want to ask you first -- and your colleague can also weigh in here -- I do want to direct Bayer's attention to its brief, where you write at Page 7, opening, "The starting point" -- talking about claim construction, after you cite, I think it's after you cite Vitronics -- "is the words of the claims which are presumed to Bayer their ordinary and customary meaning as understood by a person of ordinary skill in the art at the time of the invention. Phillips.

Then at Page 17 of your answering brief, you write the following, in Paragraph 7: Defendants attempt to characterize and obtain a finding as to the person of ordinary skill in the art, citation to the brief. First, they offer support neither for their description of the skilled artisan nor the art in which the person is skilled. Secondly, there is no extrinsic evidence before this Court, parenthetic, even the need to establish the person of ordinary skill in the art presupposes the need to interpret extrinsic evidence), nor is there an affidavit of any expert.

I am a little confused as to Bayer's position on how this Court should approach its job and the task of claim construction.

MR. BOVE: Your Honor, if I may respond.

Number one, the position of actually both parties, I believe, is that the claim terms may be addressed, in Bayer's case, Talecris' case, based on the plain meaning of the terms, ergo, no evidence of the level of skill in the art was introduced. Baxter's position is similar in the sense that no evidence of the level of skill in the art is introduced.

Ergo, the Court's dilemma -- well, if the Court requires a level of skill in the art to address this, then, as I understand Your Honor's question, what does the Court

do. Let me at least make it clear what Talecris' position is. We have not sought to introduce any extrinsic evidence on this point, as the briefs indicate.

Your Honor, a patent, as the Court is well-aware, does not need to teach what one skilled in the art knows. So we first want to look at, well, what is the basic teaching of the patent. This is, as my colleague on the other side said, very complex technology in one sense. In another sense, if you are a Ph.D., it is not very complex.

So it is Talecris' position that one skilled in the art would certainly need to be a Ph.D. They would need to have background in designing purification and manufacturing processes. After all, that is what we are talking about here in this patent. However, teams that go and perform this work also do contain clinicians, medical doctors. Indeed, that's exactly how I think both parties have designed their processes. You have to have clinical end points, as Ms. Bourke will address with respect to the second one.

You have to have a person knowledgeable about complement assays at a Ph.D level and also viral activation. Our position for the record would be a Ph.D. of one or more of those types of technical backgrounds.

What Baxter posits, as best I understand, is a

much lower level of skill, basically a line technician looking for a protocol to follow with numbers in the claim. That is not what the patent is directed to. The claim basically says, this is the teaching, this is the direction you go in, and you will be able to get the details for your particular process.

THE COURT: So it's Talecris' and Bayer's position -- Bayer can speak for itself -- that this is not the time, Markman is really not the time that the Court has to engage the resolution of that dispute. That's really more for a fact-finder potentially down the road.

MR. BOVE: Yes, Your Honor.

Your Honor, switching back into the other arguments. Let me first say, Column 5 in the patent at JA-47 in Line 51, I think Ms. Bourke will get back to this, Column 5 at JA-47 in Line 51 states, there is no strict rule for determining whether ACA level is low enough to be acceptable. That is just an important predicate for what I am about to say. Baxter's reply brief at Page 10 states, I will just read it, It is only the ACA levels in the final solution ... that must be acceptable.

We will start with that as a background. Let me then go to specific rebuttal about the increase and the decrease.

First of all, the prior art -- I am going to

address the prosecution history briefly. The prior art did not necessitate an increase in ACA to any given level. Indeed, the thrust of the prosection history was that, in fact, the prior art did not show an increase after the S/D step. That was the problem. And this patent provided the solution to it.

So there was nothing in the prior art requiring an elevation to any given level.

Secondly, the amendments. The amendments did not address any level of increase. What happened was, the word given was in the claim. And the examiner said, no, that is not good enough. I don't know what it means.

They added the words given increased. The examiner said, no, not yet. So then they deleted the word given and it ended up as an increase. This is in Step (a).

The standard, and this is what the applicant said, not what the examiner said, that the applicant, which is the key, the operative words, Salazar says the Court doesn't rely on what the examiner says. We cited Salazar in our reply brief, the standard which cured the indefiniteness rejection was the standard of the starting material before the process. That was it. It starts at a level, it elevates, and then it is reduced.

That was the basis for the applicant's position.

So we have no prior art, and actually it is very

simple. It starts, that's the starting level. And, indeed -- let me see if I can give you the page cite for that. It's not really apparent, I don't want to take more time. It is JA-98. That should be helpful to the Court.

So no prior art -- the amendments were not necessitated such that the level had to increase to any particular numerical point, and then to be reduced to any particular point, except Ms. Bourke's acceptable.

Next point. Baxter's intrinsic evidence. Your Honor, I started with Column 5. There is no fixed line for acceptability. The intrinsic evidence simply states that it rises, and remember Column 5 says any elevation is bad, as Ms. Bourke started off. Therefore, unacceptably high is really any elevation you want to try to eliminate. One skilled in the art that we just referred to would want to avoid this and bring it back down so that the human can consume it through IV.

All of these references to undesirable, unacceptable, none indicate criticality to a numeric point. None suggest that they should be read into the claim at all. They are simply descriptions, some descriptions of the prior art, undesirably higher levels of ACA. Descriptions of the examples in the patent, unacceptably high.

There is no invitation to one reading Claim 1 to read in the word unacceptable. And we submit that the case

law would counsel otherwise.

The figure. JA90, JA98 and JA134, just for the record, the figure was characterized by the patentee as illustrative, an example, not a formal drawing. That's it. To me, that is the end of the discussion on the figure. They are trying to import examples, illustrations, over and over into the claims.

Table 7 and the preferences, I am not going to take the time to go through this now, but there are stated numeric preferences, examples, as indeed a patentee should put in a patent, to help someone understand what they are teaching.

The Court well-knows, preferences examples are not read into the claim absent some clear direction to do so, which is not here because Column 5 says that there is no strict rule for doing this.

If you compare Table 7, the numbers, with the preferences, you will see that the Table 7 data in many instances after S/D are below the preference levels for acceptable. It just refutes their argument completely. I will not waste time now to say whether 43 is below 45. I invite the Court to take a look at that. I thought it was very helpful.

Let me shift now to then incubating the solution of Step (a), if I may.

First of all, no law is cited to support the proposition that there must be a particular order of processing steps in Claim 1, and, indeed, the word then suggests simply that you perform Step (b) after you perform Step (a). It doesn't mean immediately after. It just says you perform Step (a), then you perform Step (b).

Indeed, the intrinsic evidence, which I referred to in my opening, and their own brief, and Ms. Burke's demonstrative -- and there is no dispute about this -- all of this contemplates intervening processing steps between (a) and (b). There is no dispute about this.

Your Honor, just for the record, one other point of fact in the intrinsic evidence. The patent refers to sterile bulk, the solution of Step (a) has been sterilized and Step (b) is performed. And the record cites for that, which presuppose intervening processing steps, are JA-149 at Column 9, Line 12, and Column 10, Line 9. That is further support for the intrinsic evidence, which I believe is overwhelming in any event.

As to the foreign prosecution, this is Pfizer v. Ranbaxy. And we have cited to that that case. We are off into I don't know what country. But it is not relevant to this discussion today.

With that, I am going to turn the podium over to Ms. Bourke.

THE COURT: Thank you, Mr. Bove.

MS. BOURKE: Acceptable level suitable for IV administration. First, I want to address the prosecution history argument that defendants made. If Your Honor wants to refer to Page 26 and 27 of their PowerPoint presentation, that's what I am really addressing.

THE COURT: Okay.

MS. BOURKE: Their argument is wrong for three reasons. I will refer the Court to Salazar v. Procter & Gamble, 414 F.3d 1342, a Federal Circuit decision, 2005. It is cited in our briefs. And the holding for which it is cited is, Examiners' unilateral statements do not constitute clear and unambiguous disavowal of claim scope and an applicant's silence is not an acquiescence to the examiner's characterization.

So whatever the examiner did or said on Page 27 is completely irrelevant to the construction.

Number two, the applicant's statements on Page 26 were not a clear and unambiguous disavowal of claim scope. Applicant simply said look to Column 5, Lines 57 through 64, and here are some examples, the examples. The examiner never required the applicant to amend its claims to put in any numerical limitations to overcome the rejection.

And who knows what the examiner thought, and it's not relevant, but clearly, she was referred to examples

and was satisfied and withdrew the indefiniteness rejection.

Let's turn to their argument that we should read in these 45 and 60 CH-50 numbers as the acceptable levels. To me, that is just back-dooring the argument that they made for anticomplement activity which they did not address at the hearing here. But again, they are reading in a particular unit of measure. They are reading in a particular assay, hemolytic assay. And they are reading in a particular assay, that assay that was used to define those numerical limits in the patent. They even admit that these assays have inherent variability. That issue I don't think is quite properly before the Court. Maybe in an indefiniteness motion, but not on claim construction.

Quite frankly, that is exactly the reason why this Court should not read in any numerical levels to the term acceptable level for -- acceptable level suitable for IV administration.

Those numbers were developed by Bayer when it was developing its product and its process. But those numbers cannot be universally applied to every product and every process that falls within these claims.

Acceptable level suitable for administration is a clinical term. It depends on the clinical experience with that product and that process. If you look to Column 1 of the patent at Lines 15 through 20, it states, Early

pharmaceutical preparations of immuno serum globulins could not be administered intravenously due to unacceptably high incidence of adverse reactions. That is what they are talking about, the clinical events that occur from having elevated anticomplement activity. We will have experts come in at trial and explain for the jury what those exactly are.

But the claim term is clear on its face. It means what it says. Acceptable level is that which is suitable for IV administration.

THE COURT: Thank you, Ms. Bourke. All right. Okay.

Counsel, the Court appreciates the presentations and the briefing and will endeavor to issue its ruling by the end of 30 days.

I am aware that there are at least, I think, two outstanding motions. I didn't notify you that I wanted to hear argument. Quite frankly, I haven't read the briefs yet. I am essentially, I think, aware of what the issues are, what the issue in the motion to amend is, I think, the request by Baxter to include the defense of inequitable conduct, plaintiff resists that effort because I think you assert that the evidentiary support for that was improperly disclosed.

Am I misstating?

MR. BOVE: Your Honor, if I may.

THE COURT: Is that too simplistic? Do you want to talk about that in a minute?

MR. BOVE: It is a futility argument.

THE COURT: It is a futility argument.

MR. BOVE: Along with some prejudice combined. And I think the briefs are very clear on this, so that the Court will be able to get right to the point.

THE COURT: All right.

MR. BOVE: Basically, we don't know who they are accusing of doing what. And the discovery is over and this is many, many, many months after the --

THE COURT: So we are past the cutoff of fact discovery.

MR. BOVE: We are long past the cutoff for fact discovery.

THE COURT: When was the motion filed?

MR. BOVE: The motion was filed --

MR. GILLILAND: Your Honor, the motion was filed on November 1st.

THE COURT: Remind me of the fact discovery cutoff, counsel.

MR. BOVE: September 29th, Your Honor.

MR. GILLILAND: So the date for amending pleadings without leave of the Court was in early May. The production of documents and the depositions occurred after

that time. The discovery concluded at the end of September. We then filed our motion immediately thereafter.

THE COURT: How close are we to the pretrial order due date?

MR. GILLILAND: Trial is not until July of 2007.

MS. MASON: The first draft of the pretrial order is due at the end of April.

THE COURT: Then there is the motion which is perhaps a little more prickly, to disqualify. Is there anything that either side wants to say about that while you have me?

MR. BOVE: Your Honor, briefly.

THE COURT: Again, I haven't read the briefs.

MR. BOVE: I am going to direct the Court to the briefs.

THE COURT: Okay. Anything from Baxter on this?

MR. GILLILAND: Merely this, Your Honor: that the only company that Townsend ever represented was Miles, Inc. That was 15 years ago. Miles, Inc. evidently became Bayer Corporation. In the briefs, it is represented that Bayer Corporation has brought this motion to disqualify. That is not true. If the Court looks carefully at the motion that was filed, it was filed by the plaintiffs. The plaintiffs are Talecris Therapeutics and Bayer Healthcare, LLC. Neither of those companies ever was a client of

Townsend.

THE COURT: Okay. Do you want to say something?

MR. BOVE: Just briefly.

These points are addressed in the papers.

THE COURT: Is there anything else that we need to address today while we are here? Everything is running along otherwise smoothly.

All right. Counsel, have a good holiday. Merry Christmas.

(Counsel respond "Thank you.")

(Court recessed at 12:11 p.m.)